Express Mail Label No.: EV399525225US
Date of Deposit: January 7, 2005

Attorney Docket No.: 28069-606 CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Keller and Müller-Walz
SERIAL NUMBER: 10/628,965 EXAMINER: Mina Haghighatian
FILING DATE: July 28, 2003 ART UNIT: 1616
FOR: ***Dry Powder for Inhalation***

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant hereby makes of record the documents listed on the attached modified Supplemental Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are submitted herewith.

This Supplemental Information Disclosure Statement is being filed more than three months after the filing date of this application but before the mailing date of a Notice of Allowance under 37 C.F.R. §1.311. Accordingly, the fee of $180 as set forth in 37 C.F.R. §1.17(p) is enclosed.

It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims. It is also respectfully requested that the Examiner initial, sign and date, and return a copy of the signed modified Supplemental Form PTO-1449 with the next U.S. PTO communication, to evidence that the cited information has been fully considered by the U.S. Patent and Trademark Office during the examination of this application.

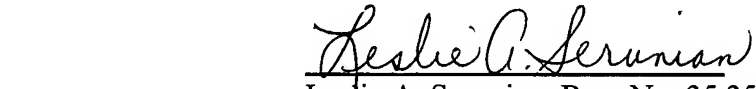
By submitting this Supplemental Information Disclosure Statement, the Applicants make no representation that: (1) a search has been performed, the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the

information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

The order of presentation of the references should not be construed as an indication of the importance of the references. The Examiner is urged to form his/her own conclusion regarding the relevance of the cited information.

Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 28069-606 CON.

Respectfully submitted,



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Modified Form 1449/PTO		
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	10/628,965
	Filing Date	07/28/03
	First Named Inventor	Keller
	Group Art Unit	1616
	Examiner Name	Haghighatian
(use as many sheets as necessary)	Attorney Docket Number	28069-606 CON

U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date

FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office	Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes	No
	B1	EP	0 416 950	Glaxo Group Limited	September 7, 1990	X	
	B2	EP	0 416 951	Glaxo Group Limited	September 7, 1990	X	
	B3	WO	93/11773	Aktiebolaget Astra	June 24, 1993	X	
	B4	WO	00/53157	Chiesi Farmaceutici S.P.A.	September 14, 2000	X	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C1	Adjei and Gupta, In Inhalation Delivery of Therapeutic Peptides and Proteins, Adjei and Gupta eds., Marcel Dekker, Inc., New York, 1997, Chapter 22, pages 625-637.
	C2	Bolhuis and Lerk (1981). *J. Pharm. Pharmacol.* 33: 790.
	C3	Braun et al. (1996). *Int. J. Pharm.* 135: 53-62.
	C4	*British Pharmacopoeia*, pages 1173-1174.
	C5	Byron, In Respiratory Drug Delivery, Byron ed., CFC Press, Inc., Boca Raton, 1990, pages 169-170.
	C6	Chowhan and Chi (1986). *J. Pharm. Sci.* 75: 534-541.
	C7	Ganderton (1969). *J. Pharm. Pharmac.* 21: 9S-18S.
	C8	Geuns et al. (1997). *European J. Pharm. and Biopharm.* 44: 187-194.
	C9	Guideline 3AQ15a, Stability Testing of New Active Substances and Medicinal Products, pages 127-141.
	C10	Guideline 3AQ16a, Stability Testing on Active Substances and Finished Products, pages 143, 145-151.
	C11	Handbook of Pharmaceutical Excipients, 2nd ed., 1994, pages 280-282.
	C12	Hickey et al. (1994). *Pharma. Tech.* pages 58, 60, 62-64, and 82.
	C13	Mahmoud and El-Shaboury (1985). *Acta. Pharm. Fenn.* 94: 125-131.
	C14	Martindale: The Extra Pharmacopeia, 28th ed., Reynolds ed., The Pharmaceutical Press, London, 1993, Abstract 6022-f.
	C15	Material Safety Data Sheet, Magnesium Stearate, Spectrum.
	C16	Meakin et al. (1995). *Int. J. Pharm.* 119: 103-108.
	C17	MIMS (Monthly Index of Medical Specialties), November 1996, pages 244-245.
	C18	MIMS (Monthly Index of Medical Specialties), October 1998, pages 271-273.

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	**Cite No.**	**Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.**
	C19	Murthy and Samyn (1977). *J. Phar. Sci.* 66: 1215-1219.
	C20	Note for Guidance on Development Pharmaceutics, European Agency for the Evaluation of Medicinal Products, Human Medicines Evaluation Unit, CPMP/QWP/155/96, January 28, 1998.
	C21	Note for Guidance on Dry Powder Inhalers, European Agency for the Evaluation of Medicinal Products, Human Medicines Evaluation Unit, CPMP/QWP/158/96, June 24, 1998.
	C22	Peart et al. (1997). *Pharm. Res.* 14: S-142-S-143, Abstract No. 1405.
	C23	Pharmaceutics: The Science of Dosage Form Design, ed. Michael E. Aulton, Churchill Livingstone, Edinburgh, London, Melbourne and New York, 1988, page 56.
	C24	Price et al. (2002). *Int. J. Pharm.* 246: 47-59.
	C25	Remington's Pharmaceutical Sciences, 18th ed., 1990, Chapter 31, pages 589,593, and 602; Chapter 76, pages 1451-1452; and Chapter 89, pages 1633, 1636, and 1637.
	C26	Respiratory Drug Delivery II, paper presented by John N. Staniforth at a meeting in Keystone, CO, March 26-30, 1990.
	C27	Statutory Declaration from Professor David Ganderton, December 15, 2003, In the Matter of an opposition by Vectura Limited to EP 1 131 059 in the name of Jago Research AG.
	C28	van Kamp et al. (1986). *Pharm. Acta. Helv.* 61: 22-29.
	C29	Young et al. (2003). *J. Pharm. Sci.* 92: 815-822.
	C30	Zeng et al., In Particulate Interactions in Dry Powder Formulations for Inhalation, Taylor and Francis, Inc., New York, 2001, Sections 1.6.7 (pages 23-24) and 5.5.6 (pages 163-165).

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____ , filed _____ , and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.